

CD HORIZON™ Anterior Spinal System**510(k) Summary****K963655**

NOV 27 1996

November, 1996

- I. Company: Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
901-396-3133
- II. Proprietary Trade Name: CD HORIZON™ Anterior Spinal System
- Classification Name: Spinal intervertebral body fixation orthosis.
- III. The CD HORIZON™ Anterior Spinal System consists of rods, screws, a set screw, and staples. In general, the system features implant components which can be used with either 5.5mm and 6.35mm Sofamor Danek rods. The 5.5mm GDLH™, 6.35mm TSRH®, and 6.35mm LIBERTY™ rods can be used with the CD HORIZON™ Anterior Spinal System. Instrumentation is also available to facilitate implantation of the device components. The purpose of the CD HORIZON™ Anterior Spinal System is to provide stabilization during the development of a solid spinal fusion. The CD HORIZON™ Anterior Spinal System implant components are fabricated from ASTM F138 (or its ISO equivalent) stainless steel and may be sold sterile or non-sterile. Stainless steel implants are not to be used with titanium alloy implant components in a spinal construct.
- IV. The CD HORIZON™ Anterior Spinal System is designed to aid in the surgical correction and stabilization of the spine. The system is intended to assist stabilization until a solid spinal fusion develops. The specific indications for the CD HORIZON™ Anterior Spinal System are the following:
1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).
 2. Pseudoarthrosis
 3. Stenosis
 4. Spondylolisthesis
 5. Spinal deformities: scoliosis, kyphosis, lordosis
 6. Fracture
 7. Unsuccessful previous attempts at spinal fusion
 8. Tumor resection
- All components of the CD HORIZON™ Anterior Spinal System are intended to be fixed/attached to the anterolateral spine by screws/staples in the thoracic and/or lumbar areas only.
- V. Mechanical test data were supplied in support of the CD HORIZON™ Anterior Spinal System 510(k) notification. The CD HORIZON™ Anterior Spinal System was declared to be substantially equivalent to several commercially available devices.